DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 8, 2015

Zevex, Inc.
Dianne Batch
Director, RA/QA
4314 Zevex Park Lane
Salt Lake City, UT 84123

Re: K142539
Trade/Device Name: Enteralite Infinity Enteral Pump Delivery Set, 1200 ML
Enteral Feeding Delivery Set
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PIF, PIO
Dated: November 28, 2014
Received: November 28, 2014

Dear Dianne Batch,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142539

Device Name
Enteralite Infinity Enteral Pump Delivery Set, 1200 ML Enteral Feeding Delivery Set

Indications for Use *(Describe)*
The devices in this product family are used to dispense liquid nutrients (feeding solution) at a preprogrammed pump or user controlled rate. These enteral feeding sets interface with the patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The devices may include a bag to contain the feeding solution and/or a spike to connect to a prefilled container.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

for

Enteral Feeding Sets

1. Submission Sponsor

Zevex, Inc.
4314 Zevex Park Lane
Salt Lake City, Utah 84123
USA
Phone: 801.201.6928
Fax: 801.264.1051
Contact: Dianne Batch, Director, RA/QA

2. Date Prepared

September 5, 2014

3. Device Identification

Trade/Proprietary Name:	EnteraLite Infinity Enteral Pump Delivery Sets 1200 mL Enteral Feeding Delivery Set
Common/Usual Name:	Enteral Feeding Sets
Classification Name:	Gastrointestinal Tubes and Accessories
Classification Regulation:	876.5980
Feeding Set Product Code:	PIF
Transition Connector Product Code:	PIO
Device Class:	Class II
Classification Panel:	Gastroenterology/Urology

4. Legally Marketed Predicate Device(s)

K012147, Zevex, Inc., Enteral Feeding Sets for Gravity and Pump Use

5. Device Description

These enteral feeding sets are designed to be used with or without an enteral feeding pump, (pump is not in scope for this 510k) model specific. Refer to diagrams below for explanation of components. The enteral sets terminate in a bonded conical connector, the ENFit connector; that is designed to be incompatible with ISO 594-1/2 and other non-enteral feeding connections. The ENFit connector is a new connector and it is anticipated that not all patient feeding tubes will be compatible with it, so the administration sets include an adapter that connects to the ENFit connector on one end while providing the traditional "Christmas Tree" shaped transitional stepped connector on the other.

6. Indication for Use Statement

The devices in this product family are used to dispense liquid nutrients (feeding solution) at a preprogrammed pump or user controlled rate. These enteral feeding sets interface with

the patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The devices may include a bag to contain the feeding solution and/or a spike to connect to a prefilled container.

7. Substantial Equivalence Discussion

The following table compares the Enteral Feeding Sets to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

In the 'Significant Differences' column of the table, list the differences between the device and the predicate and briefly justify why these differences do not raise safety and effectiveness concerns.

Table 5A – Comparison of Characteristics

Manufacturer	**Moog Medical Devices Group**	**Moog Medical Devices Group**	**Significant Differences**
Trade Name	Enteral Feeding Sets	Zevex, Inc., Enteral Feeding Sets For Gravity And Pump Use	
510(k) Number	K142539	K012147	N/A
Product Code	PIF, PIO	KNT	Updated Codes from FDA
Regulation Number	876.5980	876.5980	Same
Regulation Name	Gastrointestinal Tubes and Accessories	Tubes, Gastrointestinal (and Accessories)	Same
Indications for Use	The devices in this product family are used to dispense liquid nutrients (feeding solution) at a preprogrammed pump or user controlled rate. These enteral feeding sets interface with the patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The devices may include a bag to contain the feeding solution and/or a spike to connect to a prefilled container.	The devices in this product family are used to dispense liquid nutrients (feeding solution) at a preprogrammed pump or user controlled rate. These enteral feeding sets interface with the patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The devices may include a bag to contain the feeding solution and/or a spike to connect to a prefilled container.	The difference is in the distal (or patient) end of the device. Where the predicate terminates only in a traditional stepped connector, the proposed device terminates in a bonded ENFit connector which is designed to be incompatible with all other defined connectors available. The ENFit connector is designed to comply with ISO 80369-3. GI Tubes that are compatible with the ISO 80369-3 compliant design will be able to

Manufacturer	**Moog Medical Devices Group**	**Moog Medical Devices Group**	**Significant Differences**
Trade Name	Enteral Feeding Sets	Zevex, Inc., Enteral Feeding Sets For Gravity And Pump Use	
			connect directly to the ENFit connector. Non ISO 80369-3 compliant GI tubes will be able to connect to the transitional stepped connector which is designed to adapt to the ENFit connector.
Material	Non-DEHP PVC tubing, extruded film (bags), inlet port and outlet port; Polyethylene inlet port cap; polycarbonate connector/pump interface (cassette); silicone pump tubing segment; ABS distal (stepped) connector.	Non-DEHP PVC tubing, extruded film (bags), inlet port and outlet port; Polyethylene inlet port cap; polycarbonate connector/pump interface (cassette); silicone pump tubing segment; ABS distal (stepped) connector.	Similar; the differences between them are that the ABS formulation (HF 380) and color of the ENFit connector (purple, Remofin Violet PE43076356-ZT)) are different from the ABS formulation (CYCOLAC HMG47MD 6H3C106, pre-colored) used in the current stepped adapter.
Sterile	Non-sterile	Non-sterile	Same
Overall Design			
Length	Set length varies, tubing lengths same as predicate; connector is slightly shorter (~ 0.82" vs. ~2.0") than the current stepped adapter, but with the adapter (~1.74") the overall set length will be less than ¼" different.	Set length varies depending on configuration.	Same
Diameter	EnFit connector ID is 0.116".	Distal connector ID is 0.10".	The EnFit connector has a slightly larger ID, which has shown no negative impact on flow rates.
Single-Use	Yes	Yes	Same
Shelf Life	1-yr.	1-yr. (minimum)	Same

Manufacturer	Moog Medical Devices Group	Moog Medical Devices Group	Significant Differences
Trade Name	Enteral Feeding Sets	Zevex, Inc., Enteral Feeding Sets For Gravity And Pump Use	
Latex Free	Yes	Yes	Same
Complies with ISO 10993-1	Yes	Yes	Same

8. Non-Clinical Performance Data

The following testing has been performed to support substantial equivalence:

- Bond Strength – Passed
- Leak Testing – Passed
- Volumetric accuracy testing – Passed
- Biocompatibility – Passed
- Misconnection assessment – Passed
- Dimensional analysis – Passed
- Enteral Connector Risk Management Report – Acceptable
- Human Factors Testing – Acceptable
- Failure Modes and Effects Analysis (FMEA) – Acceptable
- Accelerated Aging – Passed
- ISO 80369-3 Testing as follows:
  - Falling drop positive pressure liquid leakage – Passed
  - Stress cracking – Passed
  - Resistance to separation from axial load – Passed
  - Resistance to separation from unscrewing – Passed
  - Resistance to overriding - Passed
  - Disconnection by unscrewing – Passed
  - Falling drop positive pressure liquid leakage after 20 cycles of connection and separation - Passed

As part of demonstrating safety and effectiveness of Enteral Feeding Sets and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Zevex completed a number of tests. The Enteral Feeding Sets meets all the requirements for overall design, functionality, biocompatibility, and confirms that the output meets the design inputs and specifications. The Enteral Feeding Sets passed all testing stated above as shown by the acceptable results obtained.

The Enteral Feeding Sets along with the ENFit connector and adapter complies with the applicable voluntary standards for biocompatibility. The devices passed all the testing in accordance with national and international standards.

9. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

10. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the Enteral Feeding Sets and the predicate devices do not raise any questions regarding its safety and effectiveness. The Enteral Feeding Sets, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.